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OFFICE OF POLLUTION PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mr. Glen F. O'Brien  
Business Manager  
Albaugh, Inc.  
121 N.E. 18<sup>th</sup> Street  
Ankeny, IA 50021

MR 32279

RE: Review of Draft Analytical Protocol Submitted Under TSCA Section 4 Dioxins/Furans Test Rule (40 CFR 766)

EPA's Office of Pollution Prevention and Toxics (OPPT) has reviewed a draft protocol for the sampling and analysis of a chemical substance listed in 40 CFR 766.25 from Pyxis Regulatory Consulting on behalf of Albaugh, Inc. which was received November 17, 1999. The identity of the test substance was claimed as confidential business information.

EPA finds that the submitted draft protocol is not complete and is not in compliance with applicable regulations for the Dioxins/Furans Test Rule (40 CFR 766 and 40 CFR 792). In particular, the protocol was submitted as an unsigned "draft" document and is not considered by EPA to be an official submission in response to the test rule.

In Section 1.0 (Project Description) of the submitted document, it is stated that Albaugh, Inc. imports the test substance from two separate sources. It is also stated that both sources utilize the same manufacturing process and the samples to be tested will be obtained from only one source (i.e., the source with the greatest volume of sales and the greatest potential for exposure to intense heat and alkalinity during manufacture of the test substance).

EPA must review detailed production process-related information from both sources of the test substance in order to judge if the manufacturing processes for the chemical are indeed the same. This EPA review will allow the Agency to determine whether testing of the subject chemical obtained from only one of the two sources will be adequate under the test rule.

To help you in developing your company's Sampling Plan, Quality Assurance Project Plan and Analytical Protocol for the test substance, you must follow, as stated in 40 CFR 766.12, EPA's 1987 *Guidelines for the Determination of Halogenated Dibenzo-p-Dioxins and Dibenzofurans in Commercial Products* (EPA-560/5-87/007) as well as the requirements found at 40 CFR 766 and 40 CFR 792.



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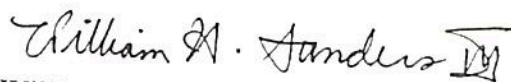
In addition, you must submit, no later than 90 days after you first import the test substance, the following information in accordance with 40 CFR 766.35(b):

- (1) full copies of all existing tests in your company's possession or control that pertain to analysis of your company's test substance for the presence of polyhalogenated dibenzo-p-dioxins or polyhalogenated dibenzofurans (see 40 CFR 766.35(b)(1));
- (2) complete copies of all TSCA Section 8(d) "unpublished health and safety studies" in your company's possession or control that pertain to polyhalogenated dibenzo-p-dioxins or polyhalogenated dibenzofurans (see 40 CFR 766.35(b)(2)); and
- (3) full copies of all of your company's TSCA Section 8(c) records of "allegations of significant adverse reactions" relating to any polyhalogenated dibenzo-p-dioxins or polyhalogenated dibenzofurans (see 40 CFR 766.35(b)(3)).

The Sampling Plan, Quality Assurance Project Plan and Analytical Protocol must be submitted to EPA within 30 days from the date of this letter.

If you have any questions about this letter or EPA's TSCA Section 4 Dioxins/Furans Test Rule, please call Ms. Oksana Pozda of my office at (202) 260-2585.

Sincerely,



William H. Sanders III, Dr. P.H., P.E.  
Director, Office of Pollution Prevention  
and Toxics

cc: Ms. Janelle Whitehouse (Pyxis Regulatory Consulting)

